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12 June 2025

s 9(2)(a)

Ref: H2025066933

Tēnā koe s 9(2)(a)

Response to your request for official information

Thank you for your request under the Official Information Act 1982 (the Act) to the Ministry of Health – Manatū Hauora (the Ministry) on 13 May 2025 for information regarding the "Effective Control Principles" document published by Medsafe. Please find a response to each part of your request below:

> *Please confirm, as a matter of urgency, that Medsafe is not approving applications for pharmacy licenses where the pharmacists said to have effective control are not also shareholding pharmacists in the pharmacy company.*

Section 55D(2)(a) of the Medicines Act 1981 states:

> 55D(2) A company may be granted a licence to operate a pharmacy if—
>
> (a) at all times more than 50% of the share capital of the company is owned by a pharmacist or pharmacists, and **effective control of the company is vested in that pharmacist or those pharmacists;**

An applicant for a licence to operate pharmacy must be able to demonstrate to Medsafe that the company complies with these requirements, for the granting of a licence to be considered.

Applications received from companies are assessed for compliance with section 55D(2)(a), and this assessment includes a check that the pharmacist(s) who hold more than 50% share capital of the company are the same pharmacist(s) who hold effective control of the company.

Please also provide us with copies of any analysis that Medsafe is applying or has relied on in assessing whether applications for pharmacy licenses comply with s 55D(2)(a) of the Medicines Act 1981 following the High Court judgment in New Zealand Independent Community Pharmacy Group v Te Whatu Ora.

The Effective Control Principles (the Principles) were developed following the High Court decision in New Zealand Independent Community Pharmacy v Te Whatu Ora - Health New Zealand and Ors [2023] NZHC 1486 (CIV-2-22-485-11), reflecting current legal interpretation of the Medicines Act 1981. Further information about the Principles can be found here: www.medsafe.govt.nz/compliance/effective-control-principles.asp

These Principles are used by Medsafe to guide assessment of an application against the effective control aspects of the pharmacy ownership requirements of section 55D(2)(a) of the Medicines Act 1981.

A Pharmacy Ownership Assessment Memo is completed for each assessment of a company against these Principles. A copy of the memo template is enclosed for reference. The assessment memos completed for each licence ownership assessment completed to date are withheld in full under section 9(2)(b)(ii) of the Act, as the release of the information would be likely unreasonably to prejudice the commercial position of the person who supplied or who is the subject of the information. I have considered the countervailing public interest in release in making this decision and consider that it does not outweigh the need to withhold at this time.

If you wish to discuss any aspect of your request with us, including this decision, please feel free to contact the OIA Services Team on: oiagr@health.govt.nz.

Under section 28(3) of the Act, you have the right to ask the Ombudsman to review any decisions made under this request. The Ombudsman may be contacted by email at: info@ombudsman.parliament.nz or by calling 0800 802 602.

Please note that this response, with your personal details removed, may be published on the Ministry website at: www.health.govt.nz/about-ministry/information-releases/responses-official-information-act-requests.

Nāku noa, nā

Chris James
Group Manager
Medsafe

Pharmacy Ownership Assessment Memo

Date:	
To:	Licensing Authority, Medicines Control
Registrar:	Choose an item.
Subject:	

Pharmacy Ownership

Legal Entity type	Choose an item.
Ownership eligibility	Choose an item.

Section 1: Effective Control

1. The Effective Control Principles (v1.1) developed by Medsafe are used to guide assessment of an application against the effective control aspects of the pharmacy ownership requirements of section 55D(2)(a.) of the Medicines Act 1981 (the Act).

2. The applicant is a company and an assessment against the Effective Control Principles has been conducted and is outlined below. Appendix 1 contains a summary of documents provided by the applicant to assist with Medsafe's assessment.

Principle 1

Pharmacist(s) must own more than 50% of the share capital of the company.

Guidance

- A pharmacist must be registered with the Pharmacy Council of New Zealand and hold a current valid annual practising certificate (APC) in the pharmacist scope of practice.
- Any additional conditions on a pharmacist's APC will be taken into consideration on a case-by-case basis.
- Shares in the company must be held by a pharmacist as an individual (e.g. not held in a trust).

Assessment notes:

Conclusion	Choose an item.

Principle 2

Pharmacist(s) must have a majority of the voting rights on the board under the company's constitution or shareholders' agreement and must have the decisive casting votes in all board matters.

Guidance

To ensure that this is the case, Medsafe must be in a position to verify this from the latest information from the company's constitution and shareholders' agreement to be supplied by the applicant.

In practice, for example, this would mean that the pharmacist(s):

- must be present and form part of the quorum in a board meeting.
- during a board meeting, must have the ability to determine the outcome of all company resolutions.

Assessment notes:

Click or tap here to enter text.

Conclusion	Choose an item.

Principle 3

Pharmacist(s) must at all times make up the majority of the board's directors, and must form the majority of the quorum for a shareholders' meeting.

Guidance

This situation must be demonstrated in the shareholders' agreement and there must be no other agreement in place (verbal or written) which enables this situation to be overridden.

The pharmacist(s) must have the ability to exert control over all resolutions made at a board level.

If a pharmacist cannot form the majority of the board (eg, when there are only two directors and one is not a pharmacist), the pharmacist must still have the ability to exert control over all resolutions made at a board level.

Assessment notes:

Click or tap here to enter text.

Conclusion	Choose an item.

Principle 4

Pharmacist(s) must have the ability to make the final decisive decision on behalf of the company, including casting the decisive vote on applicable matters in shareholder meetings.

Guidance

For example, where the majority shares of the company are held by a large or extensive number of pharmacists, there must be written confirmation from the non-director pharmacist(s) that they are represented by the pharmacist director(s) and the pharmacist director(s) retain the decisive vote at board meetings.

Applicable matters include, for example, pharmacy operational matters and contracting decisions.

Assessment notes:

Click or tap here to enter text.

Conclusion	Choose an item.

Principle 5

Pharmacist(s) must be able to make decisions at the board level that can have an impact on the health and safety of pharmacy patients.

Assessment notes:

Click or tap here to enter text.

Conclusion	Choose an item.

Section 2: Extent of interest

3. Section 55F of the Act prohibits a company or a person referred to in section 55E(3) from operating or holding a majority interest in more than 5 pharmacies.

4. Choose an item.
5. Number of pharmacies operated by the entity: Click here to enter text.
6. Compliant with section 55F(1) of the Act: Choose an item.
7. Assessment notes: Click or tap here to enter text.

Conclusion	Choose an item.

Section 3: Prescriber interest

8. Section 42C of the Act prohibits an authorised prescriber from holding an interest in a pharmacy except with the consent of the Licensing Authority.

9. Any share parcels held by a prescriber: Choose an item.
10. Prescriber and Regulatory Authority:

Prescriber	Regulatory Authority

11. Prescriber interest by way of any other instrument (e.g. turnover based rental, key money, commercial agreements): Choose an item.
12. Has the Licensing Authority previously granted consent to this prescriber interest? Choose an item.
13. Assessment notes: Click or tap here to enter text.

Conclusion	Choose an item.

Section 4: Additional ownership conditions

14. Choose an item.
15. Choose an item.

[remove this highlighted text and the following table if not applicable]

#	Existing Condition	Rationale for revocation

(3)(a.)	[None Specified]	
(3)(b.)	[None Specified]	
(3)(c.)	[None Specified]	
(3)(d.)	[None Specified]	
(3)(e.)	[None Specified]	

16. Should a decision be made to issue a licence to operate pharmacy, the following additional ownership conditions are recommended to be included:

#	Condition	Status	Section	Rationale
(3)(a.)	[None Specified]	N/A	N/A	
(3)(b.)	[None Specified]	N/A	N/A	
(3)(c.)	[None Specified]	N/A	N/A	
(3)(d.)	[None Specified]	N/A	N/A	
(3)(e.)	[None Specified]	N/A	N/A	

17. Assessment notes: Click or tap here to enter text.

Section 5: Legal advice

18. Choose an item.

Section 6: Additional information specific to the assessment

19. Choose an item.

20. Assessment notes: Click or tap here to enter text.

Assessment recommendation

21. This assessment recommends:

Choose an item.	of this ownership structure.

Appendix 1

Document summary information

Documents provided with this application (if applicable)
• Click or tap here to enter text. • Click or tap here to enter text. • Click or tap here to enter text. • Click or tap here to enter text. • Click or tap here to enter text.

Appendix 2

Legal advice summary information

Health Legal job number (if applicable)
Click or tap here to enter text.
Summary of legal advice (if applicable)
Click or tap here to enter text.